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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,847

Applicant(s)

ARMONTI ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of request for extension of time and amendment C, both dated 11-26-02 is acknowledged.

Status of Claims

Claims 1-19 have been canceled. New claims 20-27 have been presented.

The following is a new rejection in view of the newly added claims:

1. Claims 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stray-Gundersen (US '723) in view of 5,292,538 to Paul et al (US '538) and EP 387 042 (EP '042).

Instant claims are directed to a composition comprising sodium ion, magnesium ion, potassium ion, carbohydrates, zinc, calcium, vitamin C, vitamin E, rutin and biotin, which is useful for heat stress, including selective restoration of the potassium and magnesium ion.

US '723 teaches a beverage composition comprising essential electrolytes, water, carbohydrates, antioxidants and other ingredients, as a replenishing drink to a person stressed by exercise, heat or illness (cols. 4-5, summary of the invention). US '723 teaches various amounts of sodium chloride, potassium salts such as potassium phosphate, calcium, iron, vitamins A, B, C, E etc., in cols. 8-9 & examples I to IV in cols. 12-14. Vitamins C and E of US '723 read on antioxidants. The composition of US '723 contains sodium-230 mg/l, potassium-390 mg/l and calcium-120 mg/l. US '723 teaches 100 mg/l of Vitamin C, between 1 to 5 meq./liter magnesium ions (col. 9, lines 4-13) i.e., 24 mg to 120 mg/l and carbohydrate in the range of 1 to 2% for dextrose, by weight based on the total weight of the compositions (col. 9, lines 66-68 and col. 10, lines 1-11). US '723 further teaches preparing dry mixtures of the compositions (col. 12, lines 38-41).

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US '723, discusses above, does not teach zinc, manganese, biotin, rutin and beta-carotene of the instant claims.

US '538 teaches a sustained energy composition to combat the consequences of strenuous physical exercise, trauma, malnutrition etc., comprising a blend of carbohydrates, minerals, electrolytes, vitamins such as A, B complex, C, D and E, biotin, antioxidants etc. US '538 suggests adding bioavailable forms of minerals such as magnesium, zinc, manganese, boron etc., as amino acid chelates to facilitate sustained endurance and anabolism (col. 5, lines 5 through col. 6, lines 18, see table in col. 10 through col. 11). Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to add manganese, zinc, biotin and beta-carotene of US '538 in the nutritional composition of US '723, with an expectation to provide a complete nutrition with sustained energy and anabolism to a person stressed with physical exercise. The amounts of beta-carotene and biotin are mentioned in International Units and milligrams respectively, in the composition of US '538 (see example in col. 11). These amounts are different from that claimed in the instant invention. However, absent any criticality, optimizing the amounts of beta-carotene and biotin in the composition of US '732 would have been within obvious for one of an ordinary skill in the art at the time of the instant invention because US '538 suggests that biotin and beta-carotene possess antioxidant activity required to protect against the generation of free radicals and oxidative damage (col. 7, lines 43-68).

Both US '538 and US '732 teach the addition of antioxidants in their compositions to reduce the damage caused by free radicals (col. 7, lines 12-15 of '723 and col. 7, lines 61-68 of '538). However, neither of them teaches rutin in their compositions.

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EP '042 teaches rutin as an antioxidant, nutritive element and a stabilizer in various drinks, foods, beverages etc., and also as a preventive and remedy for diseases (see col. 1). EP '042 also teaches that rutin, which is also called as vitamin P, takes part in the activities of Vitamin C, causes immunopotentialization via the increase of leukocytes and thus maintains and promotes health (col. 1 and col. 10). Further, EP '042 teaches incorporating various amounts of rutin (0.01 to 5.0% w/w) (examples in col. 21-26 and col. 27, lines 1-9). In particular, EP '042 teaches rutin in the amounts of 0.01 to 2.0% w/w in foods and beverages, which is within the claimed range of 0.025 to 0.25 g/liter. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate an appropriate amount of rutin (0.01 to 2.0% w/w) of EP '042, as an antioxidant, in the beverage composition of US '723, with an expectation to reduce the damage due to oxygen free radicals, to stabilize the composition and also to maintain and promote the health of an individual who is stressed due to heat and physical exercise.

Response to Arguments

Applicant's arguments filed 11-26-02 have been fully considered but they are not persuasive.

Applicants argue that US '723 does not recognize that different electrolytes need different levels of replenishment depending on how the electrolytes were lowered or disclose all the claimed components. However, US '723 clearly recognizes the condition of loss of sweat during physical exercise, dehydration problems associated with it and the need for replacing fluid with appropriate electrolytes restored. Applicants argue that US '538 has no disclosure regarding the difference between electrolyte loss due to strenuous exertion and transpiration/perspiration.

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Therefore, applicants argue that the reference in combination with US '723 cannot possibly teach the instant invention. However, both US '723 and US '538 teach electrolyte replenishing during physical exercise and US '723 teaches loss of electrolytes through sweat (which is nothing but perspiration) during physical exercise. Thus, prior art recognizes the instant condition i.e., perspiration. Applicants' argue that compositions used to replenish electrolyte levels lowered by strenuous exercise may be unsuitable and in some situations, harmful in replenishing lowered by passive transpiration/perspiration. However, applicants have not presented any data supporting the argument. Therefore, it is the position of the examiner that the composition of US '723 and US '538 is equally useful for restoring electrolyte loss that occurred either due to passive or active (during physical exercise) sweating.

With respect to the arguments that EP '042 only teaches rutin as an antioxidant or nutritive element in drinks, foods, beverages, but does not recognize the instant electrolyte replenishment requirement during passive transpiration, it is examiner's position that while EP '042 is not in the same field of endeavor, the teachings of the above reference are reasonably pertinent to the problem of the instant application because US '723 and US '538 teach the requirement of antioxidants in replenishing drinks/beverages and EP '042 suggests that rutin augments the activities of vitamins such as vitamin C and Vitamin E and helps stabilize the composition containing these vitamins. Therefore, it would have been obvious for one of an ordinary skill in the art to incorporate an appropriate amount of rutin of EP '042 in the replenishing beverage composition of US '723 in order augment the activities of Vitamins C and E (of US '723) and stabilize the composition.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Lakshmi S Channavajjala
Examiner
Art Unit 1615
March 7, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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